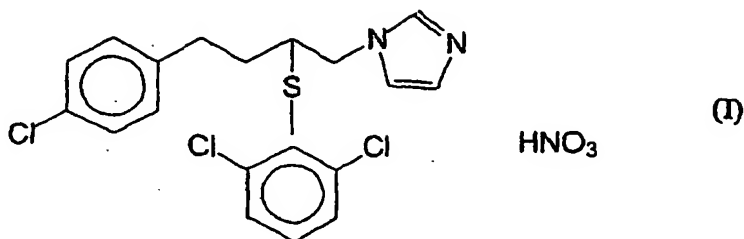


CLAIM AMENDMENTS

Claims 1 through 11 (canceled)

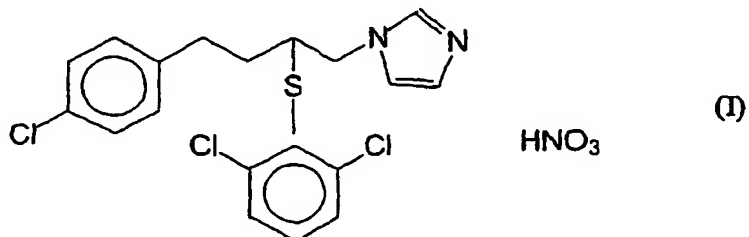
1 12. (new) High purity butoconazole nitrate salt of the
2 Formula (I)



4 containing a maximum 0.1 wt % of chemical impurities.

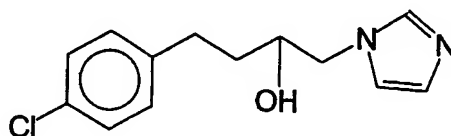
1 13. (new) High purity butoconazole nitrate salt
2 according to claim 12, wherein at least 95 % of the particles of
3 the salt are below 75 μ m in diameter, and wherein at least 99 % of
4 the particles of the salt are below 250 μ m in diameter.

1 14. (new) A process for the preparation of a high purity
2 butoconazole nitrate salt of the formula (I)



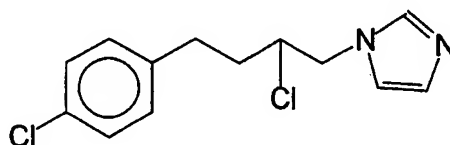
comprising the steps of:

a) reacting 1-chloro-4-chlorophenyl-2-butanol with imidazole in a mixture of a water immiscible solvent and an aqueous solution of alkali metal hydroxide or carbonate in the presence of a phase transfer catalyst to yield a compound of the Formula IV



(IV)

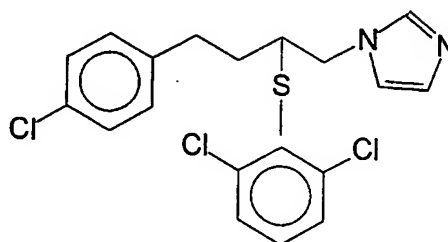
(b) reacting the compound formula of the (IV) obtained in step a), with thionyl chloride in 1,2-dichloroethane as a solvent in the presence of dimethylformamide, whereas 1-1.2 mol of thionyl chloride reagent is used based on the amount of the compound of the formula (IV) to yield a compound of the formula (V)



(V)

and

(c) reacting the compound of the formula (V) obtained in step b), with 2,6-dichlorothiophenol to obtain the compound of the Formula (VI)



(VI)

and without isolation of the compound of the Formula (VI), which remains in solution, adding nitric acid and isolating as a product the butoconazole nitrate salt of the Formula (I) having a maximum 0.1 wt % of chemical impurities.

15. (new) A process according to claim 14, wherein according to step (a) the water immiscible solvent is an aromatic hydrocarbon.

16. (new) A process according to claim 15, wherein the aromatic hydrocarbon is toluene.

1 17. (new) A process according to claim 14, wherein
2 according to step (a) the alkali metal hydroxide or carbonate is
3 respectively sodium hydroxide or sodium carbonate.

1 18. (new) A process according to claim 14, wherein
2 according to step b), thionyl chloride is used in an amount of 1.1
3 mol per mole of the compound of the Formula (IV).

1 19. (new) A process for the preparation of a high purity
2 butoconazole nitrate salt, wherein at least 95 % of the particles
3 of the salt are below 75 μ m in diameter, and whereas at least 99 %
4 of the particles of the salt are below 250 μ m in diameter, which
5 comprises the steps of:

6 (a) dissolving the butoconazole nitrate salt starting
7 material in a mixture of methanol and methyl isobutyl ketone of
8 1-1.5 : 1 ratio (v/v) to form a solution;

9 (b) adding the solution formed according to step (a) to
10 methyl isobutyl ketone cooled to a temperature between 5° and -15°C,
11 and

12 (c) isolating the desired product.

1 20. (new) A process according to claim 19, wherein
2 according to step (b) the cooling temperature is between -5°C and -
3 10°C.

1 21. (new) A process according the claim 19, wherein
2 according to step (a) the mixture of methyl alcohol and methyl
3 isobutyl ketone for dissolving the butoconazole nitrate salt
4 starting material is employed in a volume ratio of methanol/methyl
5 isobutyl ketone of 1.25 : 1.

1 22. (new) An antimicrobial pharmaceutical composition
2 comprising as active ingredient a therapeutically effective amount
3 of the high purity butoconazole nitrate salt defined in claim 12 in
4 admixture with a pharmaceutically acceptable inert carrier.

1 23. (new) The high purity butoconazole nitrate salt
2 containing a maximum 0.1 wt % of chemical impurities, prepared by
3 the process defined in claim 14.

1 24. (new) The high purity butoconazole nitrate salt,
2 wherein at least 95 % of the particles of the salt are below 75 μm
3 in diameter, and wherein at least 99 % of the particles of the salt
4 are below 250 μm in diameter, prepared by the process defined in
5 claim 19.